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# PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
930132-2207

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

| Application Number | Filed |
|---|---|
| 10/569,714 | 21 September 2009 |

First Named Inventor
Meyer et al.

| Art Unit | Examiner |
|---|---|
| 1655 | CHEN, Catheryne |

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☐ attorney or agent of record.
Registration number _____.

☑ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 48,104

/Howard C. Lee/
Signature

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27 April 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

## REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

### I. Rejection of claims 1-6 and 11-25 for obviousness is error because the interpretation of the teachings of Fischer is clearly incongruous with the meaning which would be attributed by one of ordinary skill in the art

Fischer is relied upon alone to allege obviousness of applicants' claims 1-6 and 11-22. However, all elements of the applicants' claimed invention are not taught or suggested by Fischer alone or with information which is well known to those of skill in the art. In fact, the interpretation of Fischer is at odds with the information which is well known to those of skill in the art.

First, the applicants' invention is directed toward a ***transdermal*** formulation whereas the invention of Fischer is directed toward an ***intradermal*** composition. The differences in administration is well known in the art and is even addressed by Fischer themselves in the background of their invention (see col. 1, lines 39-48).[1] As one of ordinary skill in the art would recognize that intradermal administration is intended to ***avoid*** any transdermal absorption, the Fischer reference would not be readable upon or suggestive of the applicants' transdermal formulation.

Second, Fischer is directed toward the delivery of an ***anesthetic*** whereas the applicants' transdermal formulation is directed toward delivery of an ***opioid analgesic*** from the phenanthrene group which is consistent with their disclosed methods of delivery, i.e. Fischer wants localized delivery of their anesthetic and to avoid systemic delivery whereas the applicants' invention wants to provide systemic delivery to maximize the pain relief associated with the opioid analgesic.

Moreover, Fischer recognized that the behavior of a penetration enhancer is strongly dependent on the drug (see col. 2, lines 35-41) and as such one of ordinary skill in the art would not impute the penetration activity of aloe vera with an anesthetic as being predictive of the activity with an opioid analgesic and in this instance, it is uncertain what relevance of such

[1] "In general, drug administration via the skin is divided into two categories: 1) ***transdermal*** administration and 2) ***intradermal*** administration. Transdermal administration involves transport through the skin and into the blood stream to treat systemic diseases. One the other hand, intradermal administration is intended to impart a cutaneous effect, while keeping the pharmocological effects of the drug localized to the intracutaneous regions of drug penetration and deposition. ***Ideally, intradermal absorption occurs with little or no systemic absorption or accumulation.***" (emphasis added)

predictability would be as Fischer and the applicant are directed toward inventions with opposite modes of action.

Third, Fischer also lacks a teaching for some of the elected features of the applicants' claimed invention, i.e. Fischer does not teach a matrix-type patch or that the adhesive is a synthetic rubber which in turn is comprised of styrene-butadiene-styrene block copolymer. The impropriety of this rejection appears conceded as Nielsen is used in combination with Fischer (see arguments in Section II below).

## II. Rejection of claims 1-6, 8 and 11-25 for obviousness is error because the interpretation of the teachings of Fischer is clearly incongruous with the meaning which would be attributed by one of ordinary skill in the art and Nielsen actively teaches away the reason for combining with Fischer alleged in the Office Action

The applicants' arguments with respect to Fischer made above in support of claims 1-6 and 11-25 is incorporated here by reference.

The applicants further add that Fischer is silent as to the adhesive being comprised of styrene-butadiene-styrene block copolymer. However, while Nielsen refers to an adhesive matrix of styrene-butadiene-styrene copolymer, there is no reason offered from either Fischer or Nielsen for making this combination.

Nielsen is not directed toward intradermal use as in Fischer and even if it had been directed to transdermal use, Fischer's invention actively teaches away from transdermal use. Nielsen uses their adhesive not for dermal administration of an analgesic, but for securing and sealing an ostomy (an operation where an artificial opening is formed) appliance which is unrelated to Fischer or the applicants' invention.

Moreover, there was no reason offered in the respective teachings of Fischer or Nielsen or from the generally available knowledge of those of skill in the art as to why that particular feature of Fischer needed to be modified, i.e. while it can be obvious to try and modify an invention if there are a finite number of solutions, there was no reason for one of ordinary skill in the art, lacking the applicants' claims as a blueprint, to select the use of a specific adhesive, as the necessary element to be modified; one of ordinary skill in the art could have tried any number of Fischer's other elements of their invention for modification (e.g. different active agent,

different reservoirs system, etc.) such that rather than a finite number of solutions, there was an infinite number of solution for an as undetermined problem.

**III. Previous holding that the claims represent patentably distinct inventions is incongruous with holding of obviousness over Fischer or Fischer in view of Nielsen**

The applicants' claims were previously subjected to an election of species which has not been withdrawn. This election of species required elections for five different elements:

1. The patch is a matrix-type patch
2. The adhesive is a synthetic rubber which in turn is comprised of styrene-butadiene-styrene block copolymer
3. The another penetration enhancer is an N-methyl pyrrolidone
4. The preservative is an organic acid
5. The backing comprises of polyester.

By virtue of the restriction/election of species requirement, the applicants elected invention was deemed to be patentably distinct from other elections which could have been made by the applicants.

As such, the rejections based on obviousness over Fischer or Fischer in view of Nielsen are even less supportable when it has been held that even slight permutations of the applicants' invention (e.g. use of another type of penetration enhancer besides N-methyl pyrrolidone; use of another preservative besides an organic acid, etc.) are patentably distinct inventions.